PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

18 SEP 2004

Applicant's or agent's file reference 1108WOORD01	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/02467	International filing date *(day/month/year)* 11.03.2003	Priority date *(day/month/year)* 14.03.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/454		
Applicant ALTANA PHARMA AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25.09.2003	01.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Albrecht, S Telephone No. +49 89 2399 7364

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/02467

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-4 as originally filed

Claims, Numbers

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-6,9

   because:

   ☒ the said international application, or the said claims Nos. 1-3,9 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 9 (partially) are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1-6,9 (all partially)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	-
	No:	Claims	1-9
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-9
Industrial applicability (IA)	Yes:	Claims	4-8
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1. Claims 1-3, 9 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

III.2. The attention of the applicant is drawn to the fact that for the present application only an incomplete search has been carried out (see sheet PCT/ISA/210, and in particular the last paragraph). The examination will be carried out accordingly.

III.3. Claim 9 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. In particular, the compound for use in the treatment of the therein mentioned diseases is not specified. For further processing it will be assumed that the "use of the in claim 7 indicated proton pump inhibitors for the manufacture of a medicament for the treatment of bronchitis, chronic obstructive pulmonary disease (COPD), asthma, pneumonitis or pulmonary fibrosis" is claimed.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The documents cited in the Search Report (SR) are consecutively numbered D1-D7 in this communication; this numbering will be adhered to in the rest of the procedure. The cited passage(s) for each citation will be considered unless otherwise specified.

As far as D5 (Database WPI) is concerned, the EPODOC abstract of the Italian patent IT1271434 will be considered instead in the rest of the procedure and consecutively numbered D5*.

V.1 Novelty and inventive step

V.1.1. Claims 1-9 do not appear to be novel and inventive in the sense of Articles 33(2) and (3) PCT, the reasons being as follows:

a) D1 discloses the use of rabeprazole for the treatment of asthma, laryngitis, coughing, bronchitis and apnea. As far as claim 6 is concerned, it should be noted that the feature "comprising a reference to the fact that it can be employed...." is not considered to be a technical feature and can therefore not be taken into account for the assessment of novelty and inventive step of this claim.

Thus, D1 anticipates the subject-matter of claims 1-7 and 9.

b) D2 reports the use of proton pump inhibitors, in particular omeprazole, lansoprazole, pantoprazole and rabeprazole for the treatment of inflammatory diseases in the upper respiratory tract such as rhinosinusitis, rhinitis, asthma and Widal's Syndrome.

Therefore, D2 anticipates the subject-matter of claims 1-9.

c) D3 mentions the use of the in claim 7 indicated proton pump inhibitors for the treatment of rhinotracheitis, and thus anticipates the subject-matter of claims 1-8.

d) D4 describes the efficacy of omeprazole, lansoprazole and pantoprazole in COPD (for example in cystic fibrosis) and thus anticipates the subject-matter of claims 1-9.

e) D5*, D6 and D7 state the use of omeprazole in the treatment of (bronchial) asthma and laryngitis (D6), and hence anticipate the subject-matter of claims 1-7 and 9.

V.2. Industrial Applicability

For the assessment of the present claims 1-3, 9 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

V.3. Further remarks

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D7 is not mentioned in the description, nor are these documents identified therein.